Department of Health Care Services
Counselor & Medication Assisted
Treatment Section, MS 2603
PO Box 997413
Sacramento, CA 95899-7413

APPLICATION FOR PROTOCOL AMENDMENT

INSTRUCTIONS FOR COMPLETION OF THE APPLICATION FOR PROTOCOL AMENDMENT FORM DHCS 5135 (04/16)

Return completed form to the address designated in the header above.

DO NOT USE staples on this form or on any attachments.
DO NOT USE correction tape, white out, or highlighter pen or ink of a similar type on this form. If you must make corrections, please line through, date, and initial in ink.
DO NOT LEAVE any questions, boxes, lines, or fields blank. Enter N/A if not applicable to you.

PLEASE NOTE: Read all the instructions included on this form carefully and complete each item requested. For additional information, please review the California Code of Regulations (CCR), Title 9, Division 4, Chapter 4, Subchapter 1 commencing with Section 10000, which outlines the requirements and standards for Narcotic Treatment Programs.

SECTION A — Facility Type

This section must be completed by all applicants.

Check the appropriate box for the type of facility.

Narcotic Treatment Program (NTP) – A licensed opioid addiction treatment program, whether inpatient or outpatient, which offers all of the following: evaluation, maintenance treatment and/or detoxification treatment, and other services in conjunction with replacement narcotic therapy.

Medication Unit (MU) – A facility established as part of, but geographically separate from an NTP, from which licensed private practitioners or community pharmacists dispense or administer an opioid agonist treatment medication or collect samples for drug testing or analysis.

Office-Based Narcotic Treatment Network (OBNTN) – A network of providers, that are affiliated and associated with a primary NTP, offering one or more of the following: evaluation of medical, employment, alcohol, criminal, and psychological problems; screening for diseases that are disproportionately represented in the opioid-abusing population; counseling by addiction counselors that are evaluated through ongoing supervision; and professional medical, social work, and mental health services, on-site or by referral.

SECTION B — Type of Amendment

This section must be completed by all applicants.

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Check the appropriate box(es) for the type(s) of protocol amendment for which you are applying and complete the corresponding sections for each protocol amendment.

Relocation – A change of location of a facility or of any portion of the facility.

Change in Licensed Patient Capacity – An increase or decrease in the licensed capacity for detoxification or maintenance treatment.

Addition, Reduction or Termination of Services – Any addition, reduction or termination of services.

Name of Program Sponsor – Any change in the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Change in Individual Pursuant to CCR, Title 9 §10035(a)(5) – Any change in partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Change in Physical Structure – Any change to the physical structure or floor plan of the facility including expansions or modifications to dispensing stations.

Other – All other changes in the protocol and supplemental written protocol.

SECTION C	Existing Licensee Information

This section must be completed by all applicants.

License Number – Enter the NTP license number issued by the Department for the facility with the proposed protocol amendment(s).

National Provider Identifier (NPI) – Enter the 10 digit NPI number associated with the facility. If you need additional information or do not know the NPI number, please contact the National Plan and Provider Enumeration System at https://nppes.cms.hhs.gov/NPPES/Welcome.do

Name of Legal Entity – Enter the legal entity name.

> **PLEASE NOTE:** Any business operation under a fictitious name shall submit a copy of the county filing setting forth that name.

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Corporation – For a corporation, enter the name exactly as it is filed with the Secretary of State (SOS) and as it appears on the entity's Articles of Incorporation. If you need additional information, please contact the SOS at: http://kepler.sos.ca.gov/

Limited Liability Company (LLC) – For a LLC, enter the name exactly as it is filed with the SOS and as it appears on the entity's Articles of Organization. If you need additional information, please contact the SOS at: http://kepler.sos.ca.gov/

Partnership/Limited Partnership – For a partnership or limited partnership, enter the name of the partnership exactly as it is filed with the SOS on the Statement of Partnership Authority or Certificate of Limited Partnership respectively. If you need additional information, please contact the SOS at: http://kepler.sos.ca.gov/

Sole Proprietor – For a sole proprietor, enter the full legal name of the sole proprietor.

Governmental Agency – Enter the name of the governmental agency.

Name of NTP, MU or OBNTN – If different from legal entity name, enter the name of the facility or provider.

Tax Status – Check the box which applies to your business structure for tax purposes.

Facility Street Address – Enter the exact address of the facility. A post office box or commercial box is not acceptable. If applicable, enter the room/suite/unit number of the facility.

City – Enter the city of the facility.

County – Enter the county of the facility.

Zip Code – Enter the zip code of the facility.

An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Mailing Address – If different from facility street address, enter the exact mailing address. If applicable, enter the room/suite/unit number of the mailing address.

City – Enter the city of the mailing address.

County – Enter the county of the mailing address.

Zip Code – Enter the zip code of the mailing address.

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An exact address can be verified at the United States Postal Service website:
https://tools.usps.com/go/ZipLookupAction_input

Telephone Number – Enter the contact person's telephone number, including an extension if applicable.

Fax Number – Enter the fax number assigned to the facility.

Name of Program Sponsor – Enter the person or organization responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of Program Director – Enter the name of the person who has primary administrative responsibility for operation of the NTP.

Name of Medical Director – Enter the name of the physician licensed to practice medicine in California who is responsible for medical services provided by the NTP.

SECTION D	**Relocation**

This section must be completed by applicants applying for program relocation.

PLEASE NOTE: Pursuant to CCR, Title 9, §10085(a)(2), the Department shall conduct a site visit prior to the approval of program facility relocation.

For relocation of a Department approved NTP location, additional documentation is required.

Written Statement Explaining Relocation – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the relocation of the program to the new location.
- The estimated impact that the relocation will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the relocation.

Facility and Geographical Area Form DHCS 5025 (04/16) – Complete the Facility and Geographical Area form DHCS 5025 (04/16) for the new NTP location and attach to this form.

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County Certification Form DHCS 5027 (04/16) – Complete the County Certification form DHCS 5027 (04/16) for the new NTP location and attach to this form.

Letters of Community Support – Obtain written verification of support from the community for the new NTP location and attach to this form.

SECTION E	Change in Licensed Patient Capacity

This section must be completed by applicants applying for a change in licensed patient capacity.

PLEASE NOTE: Pursuant to CCR, Title 9, §10035(d), an amendment proposing an increase in the licensed patient capacity for detoxification or maintenance treatment at a program shall be subject to the Department's determination that the program is currently in compliance with applicable State and federal laws and regulations.

For a change in the Department approved maximum licensed patient capacity, additional documentation is required.

Written Statement Explaining Change in Licensed Patient Capacity – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in licensed patient capacity.
- The estimated impact that the change in licensed patient capacity will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in licensed patient capacity.

Current Licensed Patient Capacity – Enter the Department approved maximum licensed patient capacity for maintenance and detoxification treatment.

Amount of Licensed Patient Capacity Increase or Decrease – Enter the amount of licensed patient capacity increase or decrease for maintenance and detoxification treatment.

Requested Licensed Patient Capacity – Enter the requested total licensed patient capacity for maintenance and detoxification treatment.

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Number of Deaths Reported – Enter the number of patient deaths reported in the last 90 days as required by CCR, Title 9, §10195. This information will be verified against Department records for purposes of verifying compliance.

Current Program Census – Enter the total number of patients currently receiving maintenance or detoxification treatment at the NTP.

Proposed Counselor to Patient Ratio – Enter the number of counselors per patient with the additional capacity.

> **Example:** If the program has a current total capacity of 100 patients and 10 counselors. The ratio would be 1:10.

Updated Facility Map – If any change has been made to the facility map previously provided to the Department in the protocol, attach an updated map of the NTP location.

Section F	Addition, Reduction or Termination of Services

This section must be completed by applicants applying for an addition, reduction or termination of services.

PLEASE NOTE: This section must be completed for a change in hours of operation.

For a change in Department approved services including the addition, reduction or termination of services additional documentation is required.

Written Statement Explaining Addition, Reduction or Termination of Services – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the addition, reduction or termination of services.
- The estimated impact that the addition, reduction or termination of services will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the addition, reduction or termination of services.

Section G	Change in Program Sponsor

This section must be completed by applicants applying for change in Program Sponsor.

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Name of Current Program Sponsor – Enter the person or organization currently responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units. The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Name of New Program Sponsor – Enter the person or organization that, if approved by the Department, will be responsible for the operation of the NTP and who assumes responsibility for all its employees, including any practitioners, agents, or other persons providing medical, rehabilitative, or counseling services at the program or any of its medication units and OBNTNs. The new program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director.

Business Address of New Program Sponsor – Enter the business address of the new program sponsor.

Telephone Number of New Program Sponsor – Enter the telephone number of the new program sponsor, include an extension if applicable.

Email Address of New Program Sponsor – Enter the email address of the new program sponsor.

PLEASE NOTE: For a change in program sponsor additional documentation is required.

Written Statement Explaining Change in Program Sponsor – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in program sponsor.
- The estimated impact that the change in program sponsor will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in program sponsor.

New Program Sponsor Resume – Check box to indicate that the proposed program sponsor's resume is attached to this form.

Section H	**Change in Individual Pursuant to CCR, Title 9, §10035(a)(5)**

<u>This section must be completed by applicants applying for change in individual pursuant to CCR, Title 9, §10035(a)(5).</u>

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Name of Individual – Enter the name of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Telephone Number – Enter the telephone number and extension if applicable of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Email Address – Enter the email address of the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code.

Individual Live Scan Fingerprinting Date – Enter the date that the partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, had individual live scan fingerprinting.

PLEASE NOTE: For any change in personnel pursuant to CCR, Title 9, §10035(a)(5), *additional documentation is needed*.

Written Statement Explaining Change in Individual – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.
- The estimated impact that the change in individual**),** will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Organizational Responsibility Form DHCS 5031 (04/16) – If applying for a change in partner, officer, board of director's member, or 10 percent or greater shareholder, complete the Organizational Responsibility form DHCS 5031 (04/16) and attach to this form.

Written Statement Explaining Change in Individual – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in individual.

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- The estimated impact that the change in individual will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in individual.

Staff Information Form DHCS 5026 (04/16) – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete the Staff Information form DHCS 5026 (04/16) and attach to this form.

Written Documentation of Medical Licensure – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, obtain written documentation of medical licensure and attach to this form.

Procedure for Replacement – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure of replacement of such staff member in the event of death, retirement, or prolonged sickness and attach to this form.

Procedure to Assure Appropriate Staff Time – If applying for a change in medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, complete a written statement describing the procedure to assure that appropriate staff time will be provided to the program in the event of a short-term emergency, vacation, or sickness and attach to this form.

Resume – If applying for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code, attach a resume to this form.

Section I	**Change in Physical Structure**

<u>This section must be completed by applicants applying for change in physical structure.</u>

For a change in physical structure, additional documentation is required.

Written Statement Explaining Change in Physical Structure – Check box to indicate that a written statement is attached to this form.

Statement must include:

- The proposed effective date of the change in physical structure.

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- A narrative describing the changes in physical structure.
- The estimated impact that the change in physical structure will have on the population and area served, as well as funding, budget, and staff.
- Any changes to plan of operation.
- Any other portion of the previously Department approved protocol affected by the change in physical structure.

Facility and Geographical Area Form 5025 (04/16) – Complete the Facility and Geographical Area form DHCS 5025 (04/16) to include the change in physical structure and attach to this form.

Updated Facility Map – Complete an updated facility map that includes the change in physical structure for which you are applying for and attach to this form.

Section J	**Declaration**

<u>This section must be completed by all applicants.</u>

Print Name – Enter the name of the program sponsor.

Title – *This field has been pre-filled by the Department to reflect that the form must be signed by the program sponsor.*

Signature – Program sponsor's signature.

Date – Enter the date that the application is signed by the program sponsor.

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Section A	**Facility Type**

Check one box:

- ☐ Narcotic Treatment Program (NTP) CCR, Title 9, §10030
- ☐ Medication Unit (MU) CCR, Title 9, §10020
- ☐ Office-Based Narcotic Treatment Network (OBNTN) CCR, Title 9, §10021

Section B	**Type of Amendment**

Check all that apply:

- ☐ Relocation CCR, Title 9, §10035(a)(1)
- ☐ Change in Licensed Patient Capacity CCR, Title 9, §10035(a)(2)
- ☐ Addition, Reduction or Termination of Services CCR, Title 9, §10035(a)(3)
- ☐ Program Sponsor CCR, Title 9, §10035(a)(4)
- ☐ Any change in partner, officer, director, 10 percent or greater shareholder, or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code CCR, Title 9, §10035(a)(5)
- ☐ Any change to the physical structure of the facility or floor plan including expansions or modifications to dispensing stations CCR, Title 9, §10035(a)(6)
- ☐ Other CCR, Title 9, §10035(b) _____

Section C	**Existing Licensee Information**
License Number:	National Provider Identifier (NPI):
Name of Legal Entity:	
Name of NTP, MU or OBNTN (if different than name of legal entity):	

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Section C (Continued)	**Existing Licensee Information**	
Tax Status: ☐ Corporation ☐ Nonprofit Corporation ☐ Limited Liability Company ☐ Partnership/Limited Partnership ☐ Sole Proprietor ☐ Governmental Agency		
Facility Street Address (if applicable Room/Suite/Unit):		
City:	County:	Zip Code:
Mailing Address (if applicable Room/Suite/Unit)/(if different than facility street address):		
City:	County:	Zip Code:
Telephone Number:	Fax Number:	
Name of Program Sponsor:		
Name of Program Director:		
Name of Medical Director:		

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Section D	**Relocation**
Attach the following: ☐ Written Statement Explaining Relocation ☐ Facility and Geographical Area Form DHCS 5025 (04/16) ☐ County Certification Form DHCS 5027 (04/16) ☐ Letters of Community Support	
Section E	**Change in Licensed Patient Capacity** (Complete section E if application is for increase or decrease in capacity)
Attach the following: ☐ Written Statement Explaining Change in Licensed Patient Capacity	
Current Licensed Patient Capacity:	
Amount of Licensed Patient Capacity Increase or Decrease:	
Requested Licensed Patient Capacity:	
Number of Deaths Reported in the last 90 days as required by CCR, Title 9, §10195:	
Current Program Census:	Proposed Counselor to Patient Ratio:
Updated Facility Map Attached: ☐ Yes ☐ N/A	
Section F	**Addition, Reduction or Termination of Services**
Attach the following: ☐ Written Statement Explaining Addition, Reduction or Termination of Services	
Section G	**Change in Program Sponsor**
Name of Current Program Sponsor:	
Name of New Program Sponsor:	
Business Address of New Program Sponsor:	

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Section G (Continued)	**Change in Program Sponsor**
Telephone Number of New Program Sponsor:	Email Address of New Program Sponsor:

Attach the following:

- ☐ Written Statement Explaining Change in Program Sponsor
- ☐ New Program Sponsor Resume

Section H	**Change in Individual Pursuant to CCR, Title 9, §10035(a)(5)**
Name of Individual:	
Telephone Number:	Email Address:
Individual Live Scan Fingerprinting Date:	

Attach the following for a change in partner, officer, board of director's member, or 10 percent or greater shareholder:

- ☐ Written Statement Explaining Change in Individual
- ☐ Organizational Responsibility Form DHCS 5031 (04/16)

Attach the following for a change in program director, medical director or person employed by the program under the authority of subdivision (c) of Section 2401 of the Business and Professions Code:

- ☐ Written Statement Explaining Change in Individual
- ☐ Staff Information Form DHCS 5026 (04/16)
- ☐ Written Documentation of Medical Licensure
- ☐ Procedure for Replacement
- ☐ Procedure to Assure Appropriate Staff Time
- ☐ Resume

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Section I	**Change in Physical Structure**

Attach the following documents:

☐ Written Statement Explaining Change in Physical Structure Facility Geographical Area Form DHCS 5025 (04/16)

☐ Updated Facility Map

Section J	**Declaration**

I declare under penalty of perjury under the laws of the State of California that the foregoing information and any attachment is true, accurate, and complete to the best of my knowledge and belief. I hereby further declare that I will abide by all State and federal laws and regulations governing narcotic treatment programs. I declare that I am authorized to sign this application.

Print Name:	Title: Program Sponsor
Signature:	Date:

Privacy Statement

PRIVACY STATEMENT (Civil Code Section 1798 et seq.)

All information requested in this form is mandatory. This information is required by the Department of Health Care Services (Department), Substance Use Disorder Compliance Division, Counselor & Medication Assisted Treatment Section by the authority of Health and Safety Code, Section 11839.3 and California Code of Regulations, Title 9, Section 10035. The consequence of not supplying the mandatory information requested is that application shall be deemed incomplete and, if not corrected, review of the application shall be terminated. The Department may share or provide any of the information provided in or with this form to the California Health and Human Services Agency, the California State Controller's Office, the California Department of Justice, the California Department of Consumer Affairs, the Department of Corporations, or other state or local agencies as appropriate, the Federal Bureau of Investigation, the Internal Revenue Service, the U.S. Justice Department, the United States Drug Enforcement Administration, the United States Department of Health and Human Services, and the United States Substance Abuse and Mental Health Services Administration. For more information or access to records containing your personal information maintained by the Department, contact the Counselor & Medication Assisted Treatment Section Officer of the Day at (916) 322-6682.